THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

OSTEOPLASTICS, LLC,	
Plaintiff,	
v. ZIMMER BIOMET HOLDINGS, INC., AND ZIMMER, INC.,	C.A. No JURY TRIAL DEMANDED
Defendants.	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Osteoplastics, LLC, files this Complaint and demand for a jury trial seeking relief for patent infringement by Defendants Zimmer Biomet Holdings, Inc. and Zimmer, Inc. (collectively, "Defendants"). Plaintiff states and alleges the following:

THE PARTIES

- 1. Plaintiff Osteoplastics, LLC is a limited liability company organized and existing under the laws of the state of Ohio, with its principal place of business located at 675 Alpha Drive, Suite E, Highland Heights, Ohio 44143.
- 2. Plaintiff Osteoplastics, LLC owns several patents related to methods for designing custom medical devices, including implants. These patents stem from the work of several prominent researchers associated with Case Western Reserve University ("CWRU") in the 1990s. Two of the inventors include the former Chairman of Neurological Surgery at CWRU Medical School, Dr. Robert Ratcheson, and Dr. David Dean, Ph.D., an expert in regenerative medicine.
- 3. A group of the inventors formed Osteoplastics Company, which practiced the patented inventions to successfully produce custom implants for human patients. Later, CWRU

assigned its rights in the patents to the inventors, who in turn assigned their rights to Plaintiff Osteoplastics, LLC.

- 4. On information and belief, Defendant Zimmer Biomet Holdings, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business located at 345 East Main Street, Warsaw, Indiana 46580.
- 5. On information and belief, Defendant Zimmer, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business located at 56 East Bell Drive, Warsaw, Indiana 46582.
- 6. On information and belief, Defendants provide virtual surgical planning ("VSP") services in the United States and perform the computer-aided design of custom medical devices, such as surgical guides, as part of those services.

THE ASSERTED PATENTS

- 7. On March 22, 2016, United States Patent No. 9,929,920 ("the '920 patent") entitled "Methods and Systems for Producing an Implant" was duly and legally issued by the United States Patent and Trademark Office. Osteoplastics owns the '920 patent by assignment. A true and correct copy of the '920 patent is attached as Exhibit 1.
- 8. On May 3, 2016, United States Patent No. 9,330,206 ("the '206 patent") entitled "Producing a Three Dimensional Model of an Implant" was duly and legally issued by the United States Patent and Trademark Office. Osteoplastics owns the '206 patent by assignment. A true and correct copy of the '206 patent is attached as Exhibit 2.
- 9. On June 6, 2017, United States Patent No. 9,672,617 ("the '617 patent") entitled "Methods and Systems for Producing an Implant" was duly and legally issued by the United States Patent and Trademark Office. Osteoplastics owns the '617 patent by assignment. A true and correct copy of the '617 patent is attached as Exhibit 3.

- 10. On June 6, 2017, United States Patent No. 9,672,302 ("the '302 patent") entitled "Producing a Three-Dimensional Model of an Implant" was duly and legally issued by the United States Patent and Trademark Office. Osteoplastics owns the '302 patent by assignment. A true and correct copy of the '302 patent is attached as Exhibit 4.
- 11. The '920, '206, '617, and '302 patents are collectively referred to as the Asserted Patents.

BACKGROUND

- 12. In March 2017, Osteoplastics sent a letter to the Senior Vice President, General Counsel and Secretary for Zimmer Biomet. The letter identified the '920 and '206 patents (as well as several other Osteoplastics patents) thereby providing notice of those patents. The letter also included infringement claim charts that compared Osteoplastics' understanding of Defendants' systems and methods for designing custom medical devices based on publicly-available information to representative claims in those patents. (Exhibit 5.)
- 13. The March 2017 letter requested a telephone conference with Defendants' representative to confirm Osteoplastics' understanding of Defendants' systems and methods for making custom medical devices. The letter also discussed possible licensing terms. In addition, the letter stated that "[i]f you believe that your company is not using the patented technology, we ask that you describe, in detail, the methods used by your company to make custom implants and the basis for your belief that those methods are not covered by the Osteoplastics patents." (Exhibit 5.)
- 14. In April 2017, Defendants responded to Osteoplastics' letter by stating that Osteoplastics' claim chart "shows a fundamental misunderstanding of the design and purpose" of Defendants' medical devices, but did not explain this alleged misunderstanding or provide a substantive response to Osteoplastics' infringement allegations or claim charts. (Exhibit 6).

- 15. Over the next five months, Osteoplastics and Defendants exchanged numerous communications through which Osteoplastics continued to request that Defendants provide documents or other information to address its infringement allegations. In an August 2017 communication, Defendants denied using Materialise software (which was mentioned in Osteoplastics' claim charts) to make implants. But Defendants did not respond as to whether Defendants used this software to design or manufacture other custom medical devices, such as patient specific instruments and/or surgical guides, which were addressed in Osteoplastics' claim charts. (Exhibit 7).
- 16. In September 2017, Osteoplastics sent a communication to Defendants that attached publicly-available documentation showing that Defendants used Materialise software to design their custom medical devices. (Exhibit 8).
- 17. Defendants never responded to Osteoplastics' September 2017 communication and never otherwise responded to Osteoplastics' license offer or infringement claim charts.
- 18. Since October 2018, Osteoplastics has been involved in patent litigation against 3D Systems Corporation, 3D Systems, Inc., and Medical Modeling, Inc., (collectively, "3DS") involving many of the Asserted Patents. The litigation recently settled, with 3DS agreeing to pay a royalty on their systems and methods accused of infringement.

JURISDICTION AND VENUE

- 19. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq*. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).
- 20. This Court has personal jurisdiction over Defendants because they regularly conduct business in the State of Delaware and therefore have substantial and continuous contacts within this judicial district; because they have purposefully availed themselves to the privileges

of conducting business in this judicial district; and/or because they have committed acts of patent infringement in this judicial district.

21. Venue is proper in this District pursuant to 28 U.S.C. § 1400(b).

COUNT I (Patent Infringement)

- 22. Plaintiff restates and realleges the preceding paragraphs of this Complaint.
- 23. Defendants provide products and services that involve the computer-aided design of medical devices, such as surgical guides. Based on publicly-available information,

 Osteoplastics suspected that Defendants infringed the Asserted Patents and communicated with Defendants over a period of several months regarding the suspected infringement.
- 24. Because Defendants failed to respond to Osteoplastics' inquiries for information regarding its systems and methods for designing medical devices, Osteoplastics has not been able to determine the extent of Defendants' infringement. Therefore, relying on the precedent established in *Hoffmann-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359 (Fed. Cir. 2000) and on information and belief, Osteoplastics pleads that Defendants have made, used, sold, offered for sale, and/or imported into the United States and are currently making, using, selling, offering for sale, and/or importing into the United States systems and methods for designing and manufacturing medical devices, such as Defendants' Patient Specific Instruments and Signature line of surgical guides (the "Accused Systems" and "Accused Methods") that infringe the Asserted Patents. Based on information and belief, Defendants' Accused Systems and Accused Methods include the use of Materialise's Mimics Innovation Suite of Software (including Mimics and 3-Matic software), and/or software that is materially similar.
- 25. On information and belief, Defendants have been and are infringing at least one or more claims of each of the Asserted Patents under 35 U.S.C. §§ 271(a) and/or (g). For example,

the claim charts attached hereto as Exhibit 9 describe how the Accused Systems and Accused Methods practice claim 1 of each of the Asserted Patents.

- 26. On information and belief, Defendants have known since 2017 that their activities concerning their Accused Systems and Accused Methods infringed at least two of the Asserted Patents. For example, Defendants received a letter from Osteoplastics identifying several of the Accused Patents and attaching infringement claim charts for those Accused Patents, but refused to provide a substantive response to Osteoplastics' infringement allegations and request for information relating to the Accused Systems and Methods.
- 27. On information and belief, Defendants have no reasonable basis for believing that the claims of the Asserted Patents are either invalid or not infringed by their Accused Systems and Accused Methods. Defendants did not provide any such basis despite requests for that information by Osteoplastics.
- 28. Plaintiff has been damaged as the result of Defendants' willful infringement.

 Upon information and belief, Defendants will continue to infringe the Asserted Patents unless and until it is enjoined by this Court.
- 29. Defendants have caused and will continue to cause Osteoplastics irreparable injury and damage by infringing the Asserted Patents. Osteoplastics will suffer further irreparable injury, for which it has no adequate remedy at law, unless and until Defendants are enjoined from infringing the Asserted Patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

(1) Enter judgment that Defendants have infringed one or more claims of the Asserted Patents;

- (2) Enter an order permanently enjoining Defendants and their officers, agents, employees, attorneys, and all persons in active concert or participation with any of them, from infringing the Asserted Patents;
- (3) Award Plaintiff damages in an amount sufficient to compensate it for Defendants infringement of the Asserted Patents, together with pre-judgment and post-judgment interest and costs, and all other damages permitted under 35 U.S.C. § 284;
- (4) Award Plaintiffs an accounting for acts of infringement not presented at trial and an award by the Court of additional damage for any such acts of infringement;
- (5) Treble the damages awarded to Plaintiff under 35 U.S.C. § 284 by reason of Defendants' willful infringement of at least one claim of the Asserted Patents;
- (6) Declare this case to be "exceptional" under 35 U.S.C. § 285 and award Plaintiff its attorneys' fees, expenses, and costs incurred in this action; and
 - (7) Award Plaintiff such other and further relief as this Court deems just and proper.

JURY TRIAL DEMAND

Plaintiff demands a jury trial on all issues so triable.

Dated: March 20, 2020 FISH & RICHARDSON P.C.

By: /s/ Martina Tyreus Hufnal

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